## REMARKS

Prior to this RCE, a non-final Office Action rejecting all claims was mailed July 11, 2008, responding to Applicant's RCE which included an affidavit submission with accompanying references under 37 C.F.R. 1.132, dated April 14, 2008. Examiner repeated the final rejections made in the office action prior to the RCE. Applicant timely filed an Amendment After Final Rejection concurrently with a Notice of Appeal appealing all rejections, with applicable fees on October 14, 2008, and including after-final amendments to the claims intended to place the claims in a better position on appeal by rendering the section 112 rejections moot. Applicant did not receive any notice regarding entry or refusal to enter the after-final amendments until after submission of Applicant's Appeal Brief.

Applicant received an Advisory Action refusing to admit the after-final amendments and requiring Applicant to file a new Appeal Brief based on the un-amended claims. Applicant conducted a telephone interview with Examiner and the Supervising Examiner on May 27, 2009, to discuss Examiner's refusal to enter and consider the after-final amendments. Examiner declined to reconsider his refusal to enter the amendments. A summary of that interview is included below.

Applicant has elected to withdraw the application from appeal and submit the amendments in an RCE so that the amendment may be substantively considered. Applicant submits that Examiner's refusal to enter the after-final amendments was improper, but that submitting the claim amendments through an RCE is more efficient route to address the issue than filing a petition to overcome the refusal and Applicant's financial resources are limited.

Claims 2-10 and 13 are original. Claims 14-21 were previously amended. Claim 22 was presented in a prior RCE. Claims 1, 11, 12 and 22 are currently amended.

In the last Office Action, dated July 11, 2008:

Claims 1-22 were rejected under 35 USC § 112 as indefinite in using the term "convex" in other than its ordinary meaning without giving an explicit differing definition;

Claim 22 was rejected under 35 USC § 112 as indefinite in relation to the recitation of "low profile";

Claims 1, 11, and 12 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over EP 0372127A1 to L'Esperance or US 6,042,594 to Hellenkamp.

Claims 2 and 13 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 4,173,980 to Curtin.

Claims 3-10 and 14-21 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 5,591,174 to Clark et al;

Claims 3-10 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, and Curtin, in combination with Clark;

Claims 5-10, 17, and 20-22 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with Curtin and Clark, and further in combination with Olson US 6,613,061 to Olson et al.

In this Response, regarding the Claims, all rejections are respectfully traversed, and Applicant requests continued examination to consider new amendments, and new argument addressing the new amendments and responsive to Examiner's rejections.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein. No amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Claims 1-22 are now pending in the present application. Reconsideration is

requested. In addition to the new evidence the Applicant makes the following remarks regarding individual issues:

**THE APPLICANT'S TIME TO RESPOND**

The last Office Action was mailed on July 11, 2008. Applicant timely filed a Notice of Appeal and Appeal Brief. Examiner rejected Applicant's Appeal Brief, refusing to enter the after-final amendments submitted concurrently with the Notice of Appeal. An Advisory Action and a Notice of Non-compliant Brief mailed on May 21, 2009, giving a one-month reply period which ends on June 21, 2009. This Response is timely filed. In determining whether this document is timely filed, the Patent Office is asked to note the Electronic Filing Receipt.

**SUMMARY OF EXAMINER INTERVIEW**

Applicant conducted an interview with Examiner and the Supervising Examiner on May 27, 2009, concerning Examiner's refusal to enter the after-final amendments. Examiner stated his position that the additional reference to a "concave bottom surface" contradicted the meaning of Applicant's use of "convex" in the Specification and Claims as understood by Examiner, and that the continued disagreement between Examiner and Applicant regarding the definition of "convex" and "concave" as used in the Specification and Claims indicated that the amendments did not place the claims in better condition for appeal, as required for entry of after-final amendments. Examiner also stated that the amendments raised the possibility of new matter in the claims, but did not base any actual rejection on this. Applicant stated that the additional limitation of "concave bottom surface" clarified what was clearly present in the Specification, Claims and Drawings in the first place, and that Examiner's definition of "convex" was impossible, as it would exclude the disclosed embodiment and/or render the disclosed embodiment non-functional and clearly contradicted what was disclosed. Moreover, Examiner's refusal was based on contradiction with his definition, not the definition which

would be understood by a person of ordinary skill in the art. Supervising Examiner agreed with Examiner that the amendments should not be entered as after-final amendments. No resolution was obtained.

**STATUS OF CLAIMS**

Claims 1-22 are pending.

Claims 1-22 were rejected under § 112 second paragraph for indefiniteness based upon Applicant's use of the term "convex" in the claims.

Claim 22 was rejected under § 112 second paragraph for indefiniteness based upon Applicant's use of the terms "low profile" and recitation of the element "the profile of the eye fixation portion is substantially narrow" in the claim.

Claims 1, 11, and 12 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over EP0372127A1 to L'Esperance (hereinafter "L'Esperance") or US6,042,594 to Hellenkamp (hereinafter "Hellenkamp").

Claims 2 and 13 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp as applied to claims 1, 11 and 12, and further in combination with US 4,173,980 to Curtin (hereinafter "Curtin").

Claims 3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18 and 19 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkampf as applied to claims 1, 11 and 12, and further in combination with Curtin or US5,591,174 to Clark et al (hereinafter "Clark").

Claims 5/3/1, 5/3/2, 6/4/3/1, 9/7/4/3/1, 9/7/4/3/2, 10/8/7/4/3/1, 10/8/7/4/3/2, 17 and 20-22 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin and Clark as applied to claims 3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18 and 19, and further in combination with US5,613,061 to Olson et al (hereinafter "Olson").

**STATUS OF AMENDMENTS.**

Prior to this Response, a non-final Office Action rejecting all claims was mailed July 11, 2008, responding to Applicant's RCE which included an affidavit submission with accompanying references under 37 C.F.R. 1.132, dated April 14, 2008. Examiner repeated the final rejections made in the office action prior to the RCE. Applicant timely filed an Amendment After Final Rejection concurrently with a Notice of Appeal with applicable fees on October 14, 2008, which amendments were refused entry and consideration. Applicant traverses all rejections.

Claims 2-10 and 13 are original. Claims 14-21 were previously amended. Claim 22 was presented in the prior RCE. Claims 1, 11, 12 and 22 were amended after final rejection and concurrent with the filing of the Notice of Appeal.

Claim 12 was amended to correct an informality which referred to a singular antecedent claim in plural. Claim 12 was amended to read:

> 12. The method of claims 11, further comprising:
>
> checking to see said eye fixation apparatus is centered around the cornea; and
>
> shutting off the vacuum pressure if said eye fixation apparatus is not centered around the cornea, recentering said eye fixation apparatus, and reapplying said vacuum pressure.

No new matter was added thereby and the amendment created no change in claim scope.

Claims 1-22 were rejected under § 112 second paragraph for indefiniteness based upon Applicant's use of the term "convex" in the claims. Independent Claims 1, 11 and 22 are amended to address Examiner's arguments regarding the use of "convex" in the claim language and clarify the claim scope. Specifically, Claim 1 was amended to read:

1. An eye fixation apparatus, comprising:

an eye fixation portion, wherein the eye fixation portion has an annular convex bottom contact portion, said convex bottom contact portion including a concave bottom surface, which goes upon the surface of an eyeball and encircles the cornea, and wherein the contact portion bottom surface is provided with criss-crossing channels; and

a vacuum port connected to said eye fixation portion and in communication with said criss-crossing channels such that vacuum pressure applied to said vacuum port exerts vacuum pressure through such criss-crossing channels to pull the eyeball membrane to the criss-crossing channels.

Claim 11 was amended to read:

11. A method of fixating an eye cornea for surgery, comprising:

placing an eye fixation apparatus upon the eye globe conjunctiva around the cornea, wherein the eye fixation apparatus comprises an eye fixation portion with an annular convex bottom contact portion, said convex bottom contact portion including a concave bottom surface, provided with criss-crossing channels, and a vacuum port connected to said eye fixation portion and in communication with said criss-crossing channels such that vacuum pressure applied to said vacuum port exerts vacuum pressure through such criss-crossing channels to pull the eyeball membrane to the criss-crossing channels; and

applying vacuum pressure to said vacuum port creating a pressure differential through said criss-crossing channels in relation to said conjunctiva, adhering said conjunctiva to said contact portion bottom surface.

Claim 22 was amended to read:

22. An eye fixation apparatus, comprising:

an eye fixation portion, wherein the eye fixation portion has a low-profile annular convex bottom contact portion, said convex bottom contact portion including a concave bottom surface, which goes upon the surface

of an eyeball and encircles the cornea, and wherein the contact portion bottom surface is provided with criss-crossing channels;

a vacuum port connected to said eye fixation portion and in fluid communication with said criss-crossing channels;

a first annular translation guide member with a first translation rod and first adjustment knob, adjustably connected to the eye fixation portion, wherein the first translation guide member portion can translate laterally in relation to the eye fixation portion using said first adjustment knob acting upon said first translation rod;

a second annular translation guide member with a second translation rod and second adjustment knob, adjustably connected to the first translation guide member, wherein the second translation guide member portion can translate laterally in relation to the first translation guide member and eye fixation portion using said second adjustment knob acting upon second first translation rod;

a first and a second docking screw screwed through said first and second translation guide members, respectively, and for tightening the first and second translation guide members against objects inserted into the cylindrical space formed by the first and second annular translation guide members; and

wherein, the profile of said eye fixation portion is substantially narrow so as to fit under the eye lid of a patient without use of a lid speculum.

Support for the amendments is found in the Specification at p.6, ll. 6-9: "... and on the bottom provided with an annular convex contact portion 14 *which is shaped to conform to the surface of the eye globe* and to encircle the cornea." (Emphasis added). Specific support is also found in Figs. 1, 3 and 4, clearly showing a contact portion which is convex from the outside, but which therefore includes a concave interior surface which conforms to the shape of an eyeball. Support is also found in the Specification at pp. 1-4, in the Background and Summary and Advantages, discussing the advantages of the

claimed device in reducing deformation of the cornea and eyeball and reducing rises in intraocular pressure. Based on the Specification and Drawings, a person of ordinary skill in the art would clearly have understood that a convex bottom contact portion which is shaped to conform to the surface of the eye globe includes a concave interior surface which is in contact with the corneal surface. There could be no confusion as to the scope of the claims based on the use of "convex". However, Applicant has amended the claims with more explicit language in order to narrow the issues on appeal. No new matter is added thereby, and no change in claim scope is created by the amendments.

**SUMMARY OF CLAIMED SUBJECT MATTER**

Means or step plus function analysis section. Applicant does not argue any of the pending claims as means- or step-plus-function claims.

Summary of claimed subject matter.

The present invention relates generally to devices and methods for fixating eyes for ophthalmic surgery, and more particularly to eye fixation devices and methods using vacuum pressure for fixation for guiding a surgical tool or laser.

Claims 1-10 relate to a novel apparatus for fixating the eye. Independent claim 1 recites an eye fixation apparatus having an contact portion with criss-crossing vacuum channels and a vacuum portion in communication with the criss-crossing channels. *Specification p.6-7, ll. 6-3; Figs. 1, 3, 4, #12, 14, 16, 18*. The bottom contact portion is convex to match the convex profile of the cornea. *Specification p.6, ll. 6-9; Fig. 4, #14*. The interior surface of the eye fixation portion contacts the corneal surface via the lands between criss-cross vacuum distribution channels by pulling the corneal surface toward the vacuum channels. *Specification p.6, ll. 17-20; p.11, ll. 8-19; Figs. 1, 3, 4, #14, 16.*. A vacuum port is provided in communication with the criss-crossing channels to draw the eyeball membrane to the channels. *Specification p. 6, ll. 14-17; p. 7, ll. 13-17; p.11, ll. 8-19; Fig.1, 3, #18.* .

Claims 2-9 depend from claim 1. Claim 2 includes adjustment arms which allow the surgeon to use both hands to adjust the eye fixation device in relation to the eyeball before applying vacuum, or to readjust if not correctly aligned after the first application of vacuum. *Specification p. 7, ll. 18-21; Figs. 1, 2, 5, #20.*

Claims 3, 4, 7 and 8 include first and second annular translation guide members, and translation rods with adjustment knobs, allowing the surgeon to adjust the annular opening, which is what receives surgical instruments or allows application of a surgical laser, normally in relation to one another (e.g. in a perpendicular X-Y direction), after applying vacuum to fix the fixation apparatus to the eyeball. *Specification pp. 7-10, ll. 23-18; Figs. 1, 2, 5, 6, #22, 24, 26, 28, 40, 44, 52, 56, 60, 64, 66, 68, 70*. The threaded guide rods allow precise adjustment of position to fine tune the initial positioning of the device. *Id.*

Claims 5, 6, 9, and 10 include docking screws through the first and/or second annular translation guide members so that surgical devices, such as laser sighting cones, can be inserted and locked into the annular opening, thereby fixing the surgical devices to the eyeball rather than the eyeball being forced to align with the devices. *Specification pp. 10-11, ll. 19-2; p.11, ll. 14-19; Figs. 1, 2, 5, # 72.*

Claim 22 is an apparatus claim in independent claim format which incorporates the limitations of Claims 1-10 and explicitly recites a narrow profile which fits under a patient's lid without need for a lid speculum. *Specification p. 3, ll. 6-19; p. 4, ll. 11-21; Figs. 3, 4, #14.*

Independent Claim 11 recites a method for using a novel apparatus having an annular convex bottom contact portion provided with criss-crossing vacuum channels to provide fixation of the eyeball during ophthalmic surgeries, including the steps of placing an eye fixation apparatus around the cornea and applying vacuum to the vacuum channels to fixate the eyeball. . *Specification p.6-7, ll.6-3; p.11, ll. 8-19; Figs. 1, 3, 4,*

*#12, 14, 16, 18.* Claims 12-21 depend from claim 11.

Claim 12 further includes the steps of verifying the centering of the eye fixation apparatus and adjusting if necessary by shutting off vacuum, recentering the device, and re-applying vacuum pressure. *Specification pp. 6-7, ll. 20-3; p. 11, ll. 12-14.*

Claim 13 includes the methods of claims 11 or 12 where the apparatus includes adjustment arms. *Specification p. 7, ll. 18-21; p. 11, ll. 8-19; Figs. 1, 2, 5, #20*

Claims 14 and 18 include the methods of claims 11 or 12 wherein the apparatus includes X and/or Y translation guide members. *Specification pp. 7-10, ll. 23-18; p. 11, ll. 8-19; Figs. 1, 2, 5, 6, #22, 24, 26, 28, 40, 44, 52, 56, 60, 64, 66, 68, 70.*

Claims 15 and 19 include the methods of claims 14 and 18, wherein the X and Y translation guide members are provided with threaded adjustment rods and knobs for fine adjustment. *Specification pp. 7-10, ll. 23-18; p. 11, ll. 8-19; Figs. 1, 2, 5, 6, #22, 24, 26, 28, 40, 44, 52, 56, 60, 64, 66, 68, 70.*

Claims 16, 17, 20 and 21 include the methods of claims 14, 15, 18 or 19, wherein the X and/or Y translation guide members are provided with docking screws. *Specification pp. 10-11, ll. 19-2; p.11, ll. 8-19; Figs. 1, 2, 5, # 72.*

**SUMMARY OF EVIDENCE OF RECORD**

Applicant has submitted significant evidence of record supporting a conclusion of non-obviousness, including two affidavits and several articles from peer reviewed scientific medical journals.

Affidavit of Dr. Brian Will dated January 10, 2007, and Exhibit

The first affidavit of Dr. Will, the Applicant, is dated January 10, 2007, and will be referred to as "*First Will Aff.*" Dr. Will laid the foundation for his description of the prior and differences between the claimed invention and the prior art, as well as the problems solved by his invention.

Dr. Will is a board certified Ophthalmologist with over 17 years of practice, having performed over 28,000 LASIK procedures as well as over 10,000 other ocular procedures in that time, and currently perform over 3,000 LASIK procedures per year. He has intimate experience with much of what has been considered state of the art in the field of LASIK and other keratome procedures, using lasers and microkeratome blades, including the devices incorporating the Hellenkamp (U.S. 6,042,594), Clark (U.S. 5,591,174), Curtin (U.S. 4,173,980) and L'Esperance (E.P. 0372127A1) references, or similar to these references, cited by the Examiner. This declaration is made based on my personal experience and that of my staff of two (2) ophthalmologists within the field. Dr. Will explained the novel features of his claimed invention solve problems associated with prior art devices such as described in Hellenkamp, Clark, Curtin and L'Esperance.

As explained by Dr. Will, an important aspect of the claimed apparatus and methods is the criss-cross vacuum channel of the eye-fixation portion. The criss-cross channel provides several specific advantages over the prior art. The lands between the channels provide multiple contact points spread over a wider surface, preventing the cornea, sclera and conjunctiva from being displaced into the vacuum channels and providing a more stable contact. The criss-cross channels prevent occlusion of the vacuum source during surgical procedures. The criss-cross channels markedly reduce deformation of the eye and reduce intraocular pressure – thus it is safer, more comfortable, and provides improved accuracy, especially in Femtosecond procedures. Criss-cross allow a lower profile device compared to vacuum annulus devices, obviating need for a lid speculum. Criss-cross channels allow a surgeon to reposition the fixation device, whereas vacuum annulus devices prevent repositioning due to corneal damage. Criss-cross channels permit rapid and thorough cleaning of the apparatus.

Other claimed aspects of the invention provide additional important advantages over the prior art. X-Y translation guides, see dependent claims 3-10 and 14-21, provide

adjustment capabilities built in to the fixation device which allow for superior centration properties in laser procedures, whereas prior art devices do no provide for adjustment on the fixation device itself. The addition of docking screws, see dependent claims 5, 6, 9, 10, 16, 17, 19, 20 and 21, for docking surgical devices into the fixation aperture, rather than conventional pincer type docking systems, provide smoother docking with less manual dexterity required by the surgeon.

The criss-cross channel design, claims 1 and 11, allows a lower vacuum setting to achieve the same fixation of the eye, and the narrowness and cross-orientation prevent significant displacement of the cornea, sclera and conjunctival tissue into the vacuum channels. Existing annular vacuum rings, such as taught by the Hellenkamp and Curtin references cited by the Examiner, displace significant amounts of tissue into the vacuum ring cavity, causing distortion of the eyeball, changes to the thickness of the cornea and lens, and unnecessary damage to the corneal tissues. Porous membrane devices such as described in L'Esperance are easily - inevitably - clogged by mucous, which can create an unbreakable vacuum seal that would damage the cornea when attempting to disengage it.

The criss-cross channels recited as an element of all claims reduce the potential for trauma to the cornea, a leading cause of post-LASIK complications. The incidence of subconjunctival hemorrhage has been estimated as high as 10% or more in LASIK patients. *First Will Aff.* ¶ *7.*

The low profile achieved by the criss-cross channel design eliminates the need for a lid speculum in most cases, including patients with narrow ocular fissures and orbits. Higher rates of complications from using annular fixation devices on patients with narrow ocular fissures and orbits has been documented in medical studies. *First Will Aff.* ¶ *8 (a copy of the referenced article was included for Examiner as Exh. 5 to Second Aff. Will and is included in the Evidence Appendix).* Dr. Will discussed a peer-reviewed

journal article along with the First Will Affidavit noting higher rates of complications for patients with narrow ocular fissures, in this case patients of Asian descent. *First Will Aff.* ¶ *7.*

The pores of the L'Esperance design are quite vulnerable to clogging – as is the case with any porous membrane applied to mucus surfaces. I have found, based on extensive experience in thousands of surgical procedures, that devices such as that taught by L'Esperance have at least two major drawbacks that are not mere "speculation." First, L'Esperance relies on applying suction through a porous surface backed by an annular chamber. The porous surface is subject to clogging by mucus from the conjunctiva surface – all porous surfaces are subject to clogging, which can cause loss of suction, locked in suction, and cross contamination. A second drawback of the L'Esperance reference, shared by other references cited by the Examiner, is the high profile of the vacuum chamber vault necessitated by annular designs, which requires use of lid specula for many patients which can lead to complications and discomfort.

The X-Y translation capability built in to the eye fixation apparatus, (claims 3-10 and 14-21) and the use of docking screws rather than conventional pincers (claims 5,6, 9, 10, 16, 17, 20 and 21), are also major improvements over the state of the art. The X-Y adjustment capability allows the laser or other surgical apparatus to be slaved to the eyeball, rather than vice versa (e.g. as shown in the Curtis reference, cited by the Examiner). Use of translation rods with adjustment knobs, directly on the eye fixation device, greatly reduces the manual dexterity required for adjustments, and provides for more accurate docking of the surgical apparatus.

The x-y translation capability of claims 3-10 and 14-21 allows the surgeon to dock the laser or other apparatus into the fixation device, and make simple adjustments

using the docking screws (claims 5,6, 9, 10, 16, 17, 20 and 21) while sighting to an eye with minimal distortions.

The addition of adjustment arms, as in claims 2, 13 and 22 allow a surgeon to easily maneuver the device on the eye surface without their fingers obscuring their vision. Additionally, because the surgeon's fingers are holding the adjustment arms – i.e. away from the actual conjunctival surface – there is less chance of scratches or contamination due to inadvertent contact.

Affidavit of Dr. Brian Will dated April 14, 2008, and Exhibits.

The second affidavit of Dr. Will is dated April 14, 2008, and will be referred to as the "*Second Will Aff.*" The Second Will Aff. was submitted to place evidence before the Examiner relating to the limitations of prior art devices, the differences between Applicant's invention and the prior art, and a longstanding need that has gone unsolved. In response to Examiner's argument denying that the annular vacuum ring fixation devices of the prior art, such as described in Hellenkamp, Clark and Curtin, caused complications and less-than-optimal patient outcomes (see *OA 07112008; OA 04112007*) Dr. Will submitted six peer reviewed journal articles as exhibits to the affidavit, which are reproduced in the Evidence Appendix.

Dr. Will stated that he has extensive experience in the field and what would be considered the state of the art, both by conducting thousands of surgical procedures himself and through the supervision and training of his staff of board certified ophthalmologists. The articles demonstrated a growing concern with complications related to LASIK and other ophthalmological procedures, and that research into the causes demonstrated that annular vacuum ring type eye fixation apparatus were a significant cause of complications and/or less than optimal outcomes.

Exhibit 1 to the *Second Will Aff.* is a true and correct copy of an article, Jose L. Hernandez-Verdejo, Miguiel A. Teus, Jose M. Roman, Gema Bolivar, PORCINE MODEL

TO COMPARE REAL-TIME INTRAOCULAR PRESSURE DURING LASIK WITH A MECHANICAL MICROKERATOME AND FEMTOSECOND LASER, *Investigative Ophthalmology & Visual Science*, January 2007, Vol. 48, No. 1. The intent of the authors was to compare the elevation of intraocular pressure (IOP) caused by the flap-cutting portion of LASIK procedures using a mechanical microkeratome blade versus laser microkeratome cutter. At page 1, the authors note that there is a widespread concern about the damage caused to eye structures from the increased IOP during LASIK and other procedures. The authors note that several hypothesis focus on the "suction ring" used to fix the eye during procedures. "Different hypotheses explain the posterior segment complications, with the first postulating that the mechanical stress is caused by the IOP elevation produced by the pneumatic suction ring, which may induce tangential stress on the posterior segment." Id at p.68, col 2. The authors note that real-time measurement of changes in IOP during LASIK and other procedures have been difficult to measure in the past. Id. During the experimental procedures the IOP of the porcine eyeballs was recorded continuously. Id at p. 69, col 2. "Both groups [mechanical and laser flap cuts] had an IOP increase immediately after the placement of the suction ring that was maintained during the entire surgical procedure." Id p.70, col 2. The authors noted another study which demonstrated analogous significant rises is IOP using single-port versus two-port suction rings. Id at p.70, col 2. The authors' noted that "...pressure setting for the suction ring is an important variable in determining consistent corneal flap thickness during LASIK" and that lower vacuum settings tend to produce lesser increases in IOP. Id. pp. 70-71. "Sudden increases in IOP, although well tolerated, may induce changes in the peripheral retina... These possible posterior segment complications, among others, make the knowledge of the exact IOP increase induced by surgical procedures such as laser refractive surgery increasingly important." In the field of ophthalmologic surgical procedures the term "suction ring" is generally understood to

refer to a vacuum annulus design, essentially the same as taught in Hellenkamp. Vacuum annulus designs are the industry standard at this time.

Exhibit 2 to the *Second Will Aff.* is a true and correct copy of an article, Wei-Li Chen, Yung-Feng Shih, Shu-Lang Liao, Fung-Rong Hu, Por-Tying Hung, ULTRASOUND BIOMICROSCOPIC FINDINGS IN RABBIT EYES UNDERGOING SCLERAL SUCTION DURING LAMELLAR REFRACTIVE SURGERY, *Investigative Ophthalmology & Visual Science*, December 2002, Vol. 43, No. 12. The purpose of the study was to evaluate changes in corneal structure caused by changes in IOP due to application of scleral suction rings. Suction ring related complications during lamellar refractive surgeries (including LASIK) included retinal vascular occlusion, ischemic optic neuropathy, and macular hemorrhages due to elevated IOP during surgery, and subconjunctival hemorrhage – caused by application of the suction ring. *Id at 3669, col 1.* The authors concluded that the application of the suction ring itself causes harm to a subject's eye, and that the amount of damage correlated to the length of time the suction ring was applied. The damage was due to the stresses induced by the deformation of the eye itself and consequent rise in IOP, as well as the effect of the suction ring on the scleral surface displacing into the suction ring volume. *Id at pp. 3670-71.*

Exhibit 3 to the *Second Will Aff.* is a true and correct copy of an article, Alireza Mirshahi, MD, Thomas Kohnen, MD, EFFECT OF MICROKERATOME SUCTION DURING LASIK ON OCULAR STRUCTURES, *Ophthalmology*, April 2005, Vol. 112, No. 4. The purpose was, "To study the effect of microkeratome suction on ocular structures during LASIK." The procedures were conducted using a 20.3 mm suction ring. *Id at p.646, col 1.* "The mechanics of microkeratome suction can be compared to that of blunt ocular trauma when the ocular globe is compressed and quickly released... however, at a much lower level incidence and degree." *Id at p.648, col 2.* The authors noted that more study is required to understand the precise causes. Thus, this article corroborated Dr. Will's

assertion that existing suction ring designs (as described in Hellenkamp, Clark and Curtin) are a source of trauma to the eyes of patients undergoing LASIK procedures. Applicant's invention addresses what Dr. Will asserts to be part of the cause of this trauma – the displacement of the sclera into the high chamber of suction ring designs such as Hellenkamp, and the deformation of the eyeball caused by these designs, which draw the eyeball up and into the central opening for cutting of the keratome flap.

Additionally, the authors describe increased IOP as desirable "creating a firm cornea and permitting a precise corneal flap to be cut, which is followed by laser ablation." *Id at p.645.* This is in direct contrast to the present invention, which is designed to fix the eyeball while minimizing or eliminating IOP and achieves this through minimizing distortion of the corneal tissue. Thus, the conventional literature teaches directly away from Applicant's invention.

Exhibit 4 to the *Second Will Aff.* is a true and correct copy of an article, Christina J. Flaxel, MD, Young H. Choi, MD, Michael Sheety, MD, Stephen Christopher Oeinck, CRA, Joe Y. Lee, MD, Peter J. McDonnell, MD, PROPOSED MECHANISM FOR RETINAL TEARS AFTER LASIK, *Ophthalmology*, 2004; Vol. 111, pp. 24-27. The suction ring used in the study was described: "The suction ring is a circular chamber that fixates the eye by means of a vacuum. The underside of the fixation ring has a vacuum chamber that seals against the globe." *Id at p. 26, col. 1-2.* This matches the description of the devices in Hellenkamp, Curtin and Clark and is indicative of prior art devices. The authors concluded that the mechanics of the suction ring itself may be a source of damage to eyes of patients with pre-existing vulnerabilities.

Exhibit 5 to the *Second Will Aff.* is a true and correct copy of an article, Julie M. Albietz, PhD, Lee M. Lenton, Suzanne G. McLennan, DRY EYE AFTER LASIK: COMPARISON OF OUTCOMES FOR ASIAN AND CAUCASIAN EYES, *Clinical and Experimental Optometry*, March 2005, vol 88.2. The purpose was to investigate anecdotal evidence

that LASIK patients of Asian decent experienced higher incidences of complications such as Dry Eye after LASIK. The authors found that Asian LASIK patients did suffer higher incidence of dry eye, with several potential contributing causes. One cause discussed was the smaller ocular orbit and tighter lids generally found in Asian patients compared to Caucasian patients. *Id at p. 95.* The tighter lid structure led to a higher incidence of flap cut complications and longer intra-operative prep times leading to greater damage to the ocular surface were due in large part to the tight fit of the suction ring between the lids. *Id at p. 95.* One of the advantages of the low profile apparatus of the present Application is that it fits under the eyelids of patients. Thus, the lids must accommodate only the narrow central access hole for the microkeratome blade or laser access (approximately 9-12mm) rather than the full diameter of the vacuum ring (approximately 20mm +/-). S*ee Exhibit 3 to Second Will Aff., above*). Additionally, the longer intraoperative prep times required by the use of lid specula translates into longer application of vacuum to the suction ring, which as discussed in *Exh. 2 to Second Will Aff., above*, seems to lead to increased trauma to the ocular surface and anterior structures.

Attached as Exhibit 6 to the *Second Will Aff.* is a true and correct copy of an article, Jane-Ming Lin, MD, Yi-Yu Tsai, MD, RETINAL PHLEBITIS AFTER LASIK, *Journal of Refractive Surgery*, September/October 2005, Vol. 21, p.501. The authors provide a case study of a patient suffering retinal phlebitis due to LASIK complications. The authors concluded that the cause of the retinal phlebitis may have been due to the negative effects of elevated IOP caused in part by the suction ring. The authors note that standard practice is to achieve an IOP of at least 65mmHg to support mechanical keratome flap cutting. *Id at 502, col 2.* Again, this emphasis on intentionally raising IOP is directly opposite the goal of minimizing IOP increase in Applicant's invention.

The Exhibits discussed above, as a whole, demonstrate that the existing industry suction rings, which are essentially versions of those described in Hellenkamp and Curtin/Clark, are known to be problematic in LASIK procedures although this was not known at the time of the Hellenkamp reference. The present invention seeks to reduce the damage caused by suction ring devices such as described in Hellenkamp, which are commonly used in ophthalmologic surgery.

Regarding the porous membrane and high profile chamber of L'Esperance, Dr. Will explained that the porous membrane system of L'Esperance would be subject to frequent clogging and be difficult or impossible to properly clean and sterilize. Dr. Will noted that in his 17 years of practice he had never come across a vacuum fixation device using the L'Esperance porous membrane system, which would imply a confirmation of the problems associated with L'Esperance. If the L'Esperance membrane were effective then surgeons would use it. The nature of the L'Esperance device also requires a high profile vacuum chamber. Therefore, all of the problems described, and which are supported in the professional literature, relating to high profile devices would apply especially to L'Esperance.

Dr. Will addressed the Examiner's prior stated skepticism regarding the need for lid specula when using high profile suction rings such as described in Hellenkamp, Curtin, Clark and L'Esperance. A high profile suction ring will actually not fit into many patients' eyes as their lid fissures are simply not large enough to accept the diameter or high profile vacuum ring required, which is especially true for patients of Asian descent and smaller people. With high profile apparatus described in Hellenkamp and L'Esperance the surgery either cannot be performed on such patients, or the patient must have their eyelids cut open and then sutured back together at the completion of the surgery. This significantly increases the risk of the surgeries, and leads to longer healing times for the patients.

Dr. Will described several of the negative effects of high profile devices such as Hellenkamp and L'Esperance. In many, many cases where the lids are very tight, although the surgery can be completed, the patient experiences excessive pain because the surgeon has to stretch the lid tissues in order to place the suction ring. This stretching may lead to permanent damage to the delicate lid tissue (skin, tendons and muscles) and result in development of "droopy" lids or redundant skin on the eyelids over the longer term. Such conditions would require additional surgery to repair. These are medical facts that any experienced refractive surgeon would be aware of and are outlined to the patient in every surgical consent form. In contrast, the low profile vacuum ring of the present Application allows much of the footprint of the vacuum fixation device to be inserted *under* the lids, thereby allowing surgery to be performed without these difficulties or long term risks. The low profile is achieved through the use of the criss-cross vacuum channels, which are elements of all claims.

Other problems with high profile suction rings, such as described in Hellenkamp and L'Esperance, lead to difficulties in carrying out the surgery itself. A high profile suction ring allows the patients' eyelids to gain more purchase, or force, on the ring. Patients that tend to squeeze their eyelids may dislodge the ring during the operation, which can result in irreversible eye damage in the worst case. As a result, a lid speculum is nearly mandatory when using suction rings described in Hellenkamp and L'Esperance so as to control lid pressure. The low profile device described in the present Application causes a lower level of distention of the sidewall of the eye, so the patient will not likely feel the same level of pain or pressure and so will be less likely to squeeze their lids together (and therefore less likely to displace the suction ring and less likely to cause long term damage to the lid tissues). Equally important, the eye lids cannot obtain the same level of tension on the edge of the low profile vacuum ring and this markedly diminishes the need for a lid speculum and reduces the potential for

serious intraoperative complications. The low profile device avoids this because eye lid slips comfortably over the vacuum footprint of the device.

The low profile of the claimed apparatus is achieved through the use of the criss-cross channel design. The criss-cross channels allow the use of shallower vacuum channels and distribute the vacuum over a greater area, allowing reduced vacuum levels. The Exhibits 1-6 to the *Second Will Aff.*, discussed above, all discuss the damage caused to the eye structures by higher vacuum applied through suction rings similar to Hellenkamp.

Examiner-cited Article

Examiner cited an article (Jose M. Benitez-del-Castillo, M.D., et al, DECREASE IN TEAR SECRETION AND CORNEAL SENSITIVITY AFTER LASER IN SITU KERATOMILEUSIS, *Cornea*, January 2001, Vol. 20, pp. 30-32), which is reproduced in the Evidence Appendix as Exhibit 3. The article is not relevant to any issue relating to the rejections. The study described in the article merely confirmed that dry eye is a known complication after LASIK procedures, and that artificial tears are a viable treatment in many cases. The study did not investigate causation but merely confirmed the correlation between LASIK procedures and dry eye. The study did not investigate abnormal outcomes or complications from LASIK outside typical dry eye symptoms.

## ARGUMENT

### THE SECTION 112 REJECTIONS

It is improper to reject a claim as indefinite where the scope of the claim (i.e. the metes and bounds of what would constitute infringement) would be understood by a person of ordinary skill in the art based on the claim as a whole when read in light of the Specification and Drawings. The mere fact that a claim could have been better worded does not render the claim indefinite. Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings,

370 F.3d 1354, 1366 (Fed. Cir. 2004) ("Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.") Even under the more restrictive standard of patentability announced in *Ex Parte* Miyazaki, Appeal No. 2007-3300 (BPAI Nov. 19, 2008), the recitations of the claims are not "amenable to two or more plausible claim constructions." A claim construction that reads the preferred embodiment out of the scope of the claims is not a "plausible" construction. Miyazaki, p. 11.[1] "Patentees are allowed much latitude in terminology and the language they use will be given the meaning intended by them if it can be ascertained from the context. It is immaterial that we must refer to the specifications for an understanding [of the claim recitals]." Lincoln Stores, Inc. v. Nashua Mfg. Co., 157 F.2d 154, 158 (1st Cir. 1946) (internal citations omitted). "It is settled law that the claims of a patent in order to be valid must define the patented invention with sufficient clarity that the metes and bounds thereof can be determined, but this requirement that the invention be pointed out with particularity does not preclude some latitude in claim interpretation, particularly where the meaning of what otherwise may be confusing recitals in the claims can be ascertained as here by referral to the specification and drawings." Kenmode Mfr. Co. v. U.S., 347 F.2d 315 (Ct. Cl. 1965) (internal citations omitted).

A non-standard use of a term is not indefinite if the meaning is clear when read in light of the Specification and Claims. Application of Mercier, 515 F.2d 1161, 1168-9

[1] Although Applicant cites Miyazaki as BPAI precedent, Applicant objects contending that the indefiniteness standard in Miyazaki violates binding Federal Circuit and Supreme Court precedent, and is inconsistent with the statutory requirements for patentability under 35 U.S.C. § 112, second paragraph. Nothing in the Patent Act, nor in higher court precedent, permits a different standard of patentability to applied by the USPTO as opposed to courts. The higher standards imposed by the presumed validity of an issued patent under 35 U.S.C. § 282 go to evidentiary standards and shifting burdens of persuasion, rather than statutory standards of patentability, as asserted in the Miyazaki decision. However, Applicant asserts that the rejections for indefiniteness must be reversed under either standard.

(C.C.P.A. 1975).

> "Assuming, arguendo that the phrase 'fluidized catalyst' is more often than not used to refer to a gas-suspended catalyst system, it does not follow that confusion will result when the phrase is used in a claim to refer to a finely divided catalyst in a dispersed or suspended state in a liquid phase. Whether a term used in a claim is conventional is not necessarily controlling on the question of indefiniteness. Since we are unable to see why or how there would be uncertainty over the plain meaning of the claim read in its entirety in view of the quoted portion which provides that the reaction mixture is in a liquid phase, the section 112 second paragraph rejection must be reversed."

*Id.* (Internal citations omitted.) The requirement for specificity requires only that the claim be as specific as the subject matter permits. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986) ("The claims were intended to cover the use of the invention with various types of automobiles. That a particular chair on which the claims read may fit within some automobiles and not others is of no moment. The phrase 'so dimensioned' is as accurate as the subject matter permits, automobiles being of various sizes." (Internal citations omitted.))

**A. Claims 1-22: The term "convex" is clearly understood.**

The Examiner rejected claims 1-22 under § 112 second paragraph stating that Applicant has misused the term "convex." *OA 07112008 at p.9.* As an initial matter, the Examiner never raised issue with this term in the prosecution of the application until after Applicant's submission of the first RCE, in an Office Action dated 04112007, so Applicant submits the use of the term is (and was) clearly understood. *See OA 09072005* (no mention of confusion over "convex"); *OA 07142006* (no mention of confusion over "convex"). The Examiner's dictionary definition of "convex" as "curved or rounded like the exterior of a sphere", *see OA 07112008 at p.9* is not incorrect, but the issue raised by the Examiner is simply one of orientation – a convex object may include

a concave interior surface from the reverse perspective so they are not mutually exclusive. Examiner's proffered definition does not acknowledge this inherency (actually precludes this inherency) and renders absurd results. It also directly contradicts the disclosed embodiment, and is simply not plausible.

The "bottom portion" of the fixation device is convex, *see claims 1, 11 and 22, Figs. 1, 3, 4 #14*, although the bottom *surface* is concave. The eyeball is essentially a ball – not perfectly spherical – i.e. convex. The eye fixation apparatus described in the application includes an "annular convex bottom contact portion" – i.e. annular to include an opening for access by a surgeon, and convex to match the convex contours of the eyeball. It necessarily follows that the inside of a convex annulus will be concave – it is merely a matter of reference point. So reference to convex in this context, with reference to an eyeball, the Specification, the drawings, and the knowledge of a person of ordinary skill in the art, obviously would understand that one could refer to the overall shape as convex or concave and render the same meaning. As the Examiner raised this issue only after having numerous exchanges and discourses with Applicant via office actions without confusion, Applicant submits that "convex" as used in the Specification, Drawings and Claims is clear. Applicant presented these arguments to the Examiner. *See RCE 04142008 at pp.10-11.* Applicant, however, amended the claims after final rejection to specifically refer to the "concave contact surface", so this rejection should now be moot, *see claims 1, 11 and 22*.

Convex also is elucidated by reference to the Specification explaining that the eye fixation portion is low profile in order to fit under the patient's eyelids, so as to obviate the need for a lid speculum to hold back the eyelid. Thus, the "bottom contact portion" of the "eye fixation portion" is convex, so as to match the convex curvature of the eyeball and fit under the eyelids, whereas the inside surface of the "bottom contact portion" is concave. This is clear when the claim language is read in light of the

Specification and Drawings as required. An object can be both convex and concave simultaneously, it is merely a matter of reference point, which reference point is provided by the Specification and Drawings.

In Miyazaki, the BPAI refused to read in limitations from the disclosed preferred embodiment into the claims in order to find them definite. Here, however, there is no need to read in limitations from the preferred embodiment to render the claims definite, but rather the Examiner is attempting to impose a limitation into the claims which would render the preferred embodiment outside of the claim scope. Moreover, the issue is not one of narrowing or altering the definition of a word, but rather simply orientation when using the word. An object that is convex from the outside is concave on the inside. Describing the object as convex is therefore not ambiguous. Moreover, the Examiner is attempting to define "convex" in isolation from the wording of the entire claim itself. The claim language recites "... an annular convex bottom contact portion which goes upon the surface of an eyeball and encircles the cornea..." Construing this language as requiring a convex exterior shape as well as a convex interior surface is simply not plausible based on the plain claim language. The Examiner's proffered construction is even less plausible when read in light of the Specification and Drawings. There is no "plausible alternative meaning" in this case, as required under the Board's heightened standard of definiteness. Miyazaki, pp. 10-11.

Notably, the rejected claims include precisely that which the BPAI found lacking in the Miyazaki decision where "because the relative position of the user and printer are not well-defined in the claim, the claimed height of the paper feeding unit does not present a structural limitation on the height at all." Miyazaki, pp. 15-16. In stark contrast, claims 1, 11 and 22 recite a convex eye fixation part "...which goes upon the surface of an eyeball and encircles the cornea..." Therefore, the orientation of "convex" vs. "concave" used by the Applicant is clear from the context and not subject to other

*plausible* interpretations.

The only plausible reading is that "convex" refers to the shape from an external perspective, because a convex interior surface could not "[go] upon the surface of an eyeball". Applicant, however, has amended the claims to remove this issue, adding a specific reference to the interior surface of the bottom contact portion.

**B. Claim 22: "low profile" and "the profile of the eye fixation portion is substantially narrow" are clearly understood.**

The Examiner rejected claim 22 under § 112 second paragraph stating that "low profile" is unclear as the total height of the device, including the X-Y translation guide members, would be too high to fit under an eyelid. Applicant submits the Examiner misreads the claim. *OA 07112008 at p. 9.* It is the "eye fixation portion" which specifically includes the "low profile... substantially narrow so as to fit under the eye lid of a patient without the use of a lid speculum." *See Claim 22.* The claim does not recite that the entire device fits under a patient's eyelid, but merely the portion extending outward with the criss-cross vacuum channels - the "annular convex contact portion 14" is bottom portion which fixes the eye by applying vacuum to the criss-crossing channels. *See claim 22; Specification at p.6, ll. 6-9; Figs.1, 3, 4, #14.*

The Examiner misconstrues the reference to "profile" as requiring the vertical torroidal portion, which provides access for surgical instruments and can provide attachment points for X and Y translation guide members, to fit under the eye lid is incorrect when read in light of the Specification and Drawings. The Examiner's reliance on the measured proportions of Fig. 4 (*see OA 07112008 at p.9*) ignores the fact that such drawings and figures are not to scale but are necessarily distorted to enable reference to particular features. The Specification specifically points this lack of scale out. *See Specification, p.5, ll. 17-22.* The Examiner's measurements of the figures provided is therefore not applicable.

The need for a lid speculum is obviated in the present invention because the bottom contact portion, which is what grips the surface of the eyeball, does not require a hollow annulus above that portion in order to distribute vacuum along the surface area contacting the eye. *See Specification at p.4, ll.11-13; First Aff. Will ¶8; Second Will Aff. ¶¶14-18*. This allows the eyelids to close to a degree over this thin lip, shown as # 14, in Fig. 4. The central open portion of the annulus which provides the access for surgical instruments and additional elements such as the translation guide members and docking screws, is sized to accept the surgical apparatus – which is essentially fixed. Prior art devices, such as L'Esperance (*see Fig. 1*), Hellenkamp (*see Fig. 2*) and Curtin (*see Fig. 2*), cited by the Examiner under 103(a) rejections, require a vertical vacuum annulus over the contact area as well as the central vertical annulus providing surgical access. It is this vacuum annulus of prior art devices which is eliminated by the use of criss-cross channels which can extend laterally through a thin extending lip. Applicant made this clear through the Specification, and more so through his affidavit which described in detail the problems caused by prior art devices and how the present invention solves these problems through the use of low profile criss-cross channels. See Specification at p. 3 ll. 8-10 describing the need for a "low profile fit[ting] comfortably under the eye lid"; and at p. 4 ll. 12-14 describing an advantage of the present device as being low profile and not requiring need for a lid speculum, thereby distinguishing the present invention from existing devices.

Section 112 paragraph 2 requires the claims to be sufficiently clear to enable a person to understand, in light of the Specification and Drawings, what the applicant regards as the invention. This does not impose a requirement to provide detailed dimensions, but allows the use of relative dimensions or references, so long as they are adequately clear. The use of language such as "substantially narrow" in relation to a reference which provides basis by which a person of ordinary skill in the art can

understand the structure as in "so as to fit under the eye lid of a patient without the use of a lid speculum" is sufficiently clear. *See* Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986) ("A decision on whether a claim is invalid under § 112, 2d ¶, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.") Applicant submits that the claim, read in light of the specification and drawings, with the knowledge of a person of ordinary skill in the art, is clear and definite and has proper antecedent basis.

**THE SECTION 103(A) OBVIOUSNESS REJECTIONS**

The Examiner's rejections go beyond merely hindsight analysis and actually read teachings and elements into the cited prior art which are not present under any reasonable reading of the references.

The standard under Section 103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In re O'Farrell, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l v. Teleflex, Inc., 127 S.Ct. 1727, 1742, 167 L.Ed.2d 705 (2007). The Examiner bears the initial burden in the case of Section 103(a) obviousness rejection which requires the Examiner to put forward evidence that the invention as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention. In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984) , citing In re Warner, 379 F.2d 1011, 1016 (CCPA 1967). Where the Examiner relies on a single prior art reference for an obviousness rejection, which does not describe every limitation of the claim, the Examiner must demonstrate how a person of ordinary skill in the art would have been motivated to modify the reference to achieve the invention without the benefit of hindsight, just as with a combination of references.

Where an Applicant submits evidence an Examiner cannot simply deny such evidence without citation to reference or submission of an affidavit himself detailing the bases of his knowledge and expertise. MPEP 2142; In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997). Although the Supreme Court rejected rigid application of the "suggestion, motivation, teaching test" applied by courts in the past, it can still be a useful starting point for evaluation and to prevent hindsight analysis, so long as it is not applied rigidly and the evaluator maintains the framework of the analysis laid down in Graham v. John Deere Co., 383 U.S. 1 (1966). KSR, 127 S.Ct. at 1242. Moreover, the Examiner cannot rely on the applicant's disclosure in any way in making this *prima facie* case. MPEP 2143. The foundational facts for the *prima facie* case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. at 17-18; Miles Lab., Inc. v. Shandon Inc., 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness. Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 231, 236 (Fed. Cir. 1983). Each obviousness determination rests on its own facts. In re Durden, 226 USPQ 359, 361 (Fed. Cir. 1985).

"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986). Here, the Examiner relies upon conclusory statements that combining the references "would be obvious to one of ordinary skill in the art." The Examiner thus failed to establish a *prima facie* case of obviousness to support rejection.

Further, regarding all of the § 103(a) rejections, the Examiner failed to make specific findings as to the level of ordinary skill and the differences between the prior art

and the claimed invention.

No prior art references produced by the Examiner disclose an eye fixation apparatus with criss-crossing vacuum channels. Not individually. Not in any combination. The Examiner's rejections under Section 103 are based on the argument that criss-crossing vacuum channels are no different than a prior vacuum annulus ring (Hellenkamp, Curtis and Clark) or a flat porous membrane (L'Esperance) because these prior art devices are "presumed valid" and therefore work without flaws. The Examiner's argument continues that, because the prior art works without flaws, Applicant therefore must prove the defects of the prior art with references. Applicant submits that this burden is completely incorrect and inappropriate. Nevertheless, Applicant has provided references, from peer-reviewed scientific journals, demonstrating that prior art devices cause significant complications. Applicant has further provided details of his own experience as a board-certified ophthalmalic surgeon with thousands of procedures under his belt, concluding that prior art devices cause complications and reduced outcomes. The Examiner rejects this evidence without support. The Examiner did not cite a single reference which supports his arguments. The Examiner produces no affidavit demonstrating that he would have superior knowledge in the field. The Examiner simply rejects the evidence.

The burden lies with the Examiner to demonstrate a *prima facie* case of obviousness, meaning that some combination of prior art references discloses the claimed elements. No such combination exists. Applicant has more than met the burden of demonstrating non-obviousness - a burden that is not Applicant's to meet in the first place. Unless the Examiner produces evidence of record that demonstrates that annular vacuum rings work exactly the same as Applicant's claimed invention, or that porous membranes backed by annular vacuum chambers work exactly as Applicant's claimed invention, and without any flaws, then the rejections must be withdrawn.

**THE REFERENCES**

The Examiner relies on L'Esperance and/or Hellenkamp as a basis for every rejection under § 103(a). *OA 07112008 at pp.9-11.* The Examiner acknowledges that neither L'Esperance nor Hellenkamp teach the use of criss-crossing vacuum channels, which is an element of all claims. *OA 07112008 at p. 9.*

**L'Esperance.** L'Esperance discloses an apparatus for modulating a laser beam applied to an eye lens to ablate the surface for altering the lens curvature, including an eye fixation apparatus with a vertical vacuum annulus 10 over a porous membrane 11 which is in contact with the corneal surface. *L'Esperance, Fig. 1, and col. 4, ll. 26-37.* The porous membrane 11 is subject to clogging by mucous from the corneal surface. *First Will Affidavit, ¶ 9* ("Based on my experience the pores of the L'Esperance design are quite vulnerable to clogging - as is the case with any porous membrane applied to mucus surfaces."); *Second Will Affidavit, ¶ 13.* ("Among other things, it is my professional opinion that the porous membrane with vacuum on one side and mucus on the other would be subject to frequent clogging and be difficult or impossible to properly clean and sterilize.")

L'Esperance does not teach adjustment arms connected to an eye fixation device. L'Esperance does not teach X and Y translation guide members or corresponding translation rods. L'Esperance does not teach the use of docking screws. L'Esperance does not teach shutting off vacuum, recentering the eye fixation portion, and reapplying vacuum pressure. L'Esperance does not teach a low-profile eye fixation portion so as to fit under the eye lid of a patient.

**Hellenkamp.** Hellenkamp teaches an eye fixation apparatus using a conventional annular vacuum ring, with "suction enhancement assembly 40" inserted into the vacuum ring to prevent occlusion of the vacuum port. *Hellenkamp, Fig. 4, #40, and col. 7, ll. 59-67.* The suction enhancement assembly includes vacuum ports 55

distributed along insert 40. When vacuum is applied through vacuum port 32, the sclera is displaced into the vacuum annulus defined by 26, 27, and 42, until the sclera is drawn against insert 40. *Hellenkamp col. 5, ll. 1-5; col. 8, ll. 54-60; Fig. 4.* The sclera is not prevented from displacing into the vacuum annulus, but merely from being drawn in far enough to block vacuum port 32. No change to the profile of the conventional vacuum ring is taught by Hellencamp - rather it is a conventional annular vacuum ring. Compare Hellenkamp Figs. 1 and 2, labeled "Prior Art", to Hellenkamp Figs. 4 and 5. A lower profile would actually be incompatible with the insert 40, as the vacuum annulus must have sufficient volume to receive the insert 40 and still provide an unfettered annulus volume 42 above insert 40. *Hellenkamp, Fig. 4, #40, and col. 7, ll. 59-67.* Hellenkamp teaches that the eyeball will bulge upwards into aperture 25 due to the induced distortion. "Specifically, as the suction force is applied to the assembly, the inter-ocular pressure within the eye bulges so as to urge the eye upwardly and into the positioning segment 20." *Hellenkamp, col. 8, ll. 58-61.*

Hellenkamp does not teach criss-cross vacuum channels. Hellenkamp does not teach adjustment arms connected to an eye fixation device. Hellenkamp does not teach X and Y translation guide members or corresponding translation rods. Hellenkamp does not teach the use of docking screws within an eye fixation device. Hellenkamp does not teach shutting off vacuum, recentering the eye fixation portion, and reapplying vacuum pressure, and actually precludes such a method, as discussed below. Hellenkamp does not teach a low-profile eye fixation portion so as to fit under the eye lid of a patient.

**Curtin**. The Examiner relied on Curtin in combination with L'Eperance or Hellenkamp, and further in combination with Clark and Olson. *OA 07112008 at pp.10-11.* Curtin teaches a conventional annular vacuum ring, essentially the same as Hellenkamp, as part of a grinder apparatus which reshapes the cornea by grinding away corneal tissue. *Curtin, col. 5, ll. 46-51* ("It includes a circumcorneal suction ring 122

which is a conventional device known in ophthalmic practice. This device includes an annular, hollow ring 124 which has an open bottom side which is applied to the surface of the eyeball around the cornea.") Curtin does not teach an adjustment arm, but rather teaches an eye fixation apparatus locked to a base unit which cannot be moved independently. *Curtin Fig. 1, #122, 128*. In Curtin, the "arm" referred to by the Examiner 128 (*OA 07112008 at p.11*) is fixed at its base, which also fixes the eye fixation portion - i.e. the vacuum ring - in space. Minor adjustments may be made, but essentially the eyeball must be adjusted to the vacuum ring rather than adjusting the vacuum ring to the patient's eyeball. *See Curtin, Fig. 2*.

Curtin does not teach the use of criss-cross channels, nor any other eye fixation device beyond a "conventional" annular vacuum ring. Curtin does not teach X and Y translation guide members adjustably connected to an eye fixation portion, nor translation rods to adjust translation guide members. Curtin does not teach the use of docking screws within an eye fixation device. Curtin does not teach shutting off vacuum, recentering the eye fixation portion, and reapplying vacuum pressure. Curtin does not teach a low-profile eye fixation portion which fits under the eye lid of a patient.

**Clark et al.** Clark teaches apparatus and methods to calibrate the blade extension of a keratome instrument. *Clark, Abstract*. Clark discusses X and Y adjustment only in the context of the disclosed calibration apparatus, referring to Figs. 1-3 (*Clark, col.4, starting at line 23*). Clark teaches the use of a specialized base platform (*Clark, Fig. 1, #14 "fixture"*) and a "magnifying element" 16 (i.e. a microscope). Fixture 14 is moved to a reference point, then adjusted along an x-axis and a y-axis with the resulting measured displacement providing precise actual calibration measurements of the keratome instrument blade depth. *Clark, col. 7, ll. 4-54*. The X and Y translation is performed away from the patient, away from any eye fixation apparatus, and the apparatus cannot be used to adjust the position of an annular translation member on an

eye fixation portion for surgery. *Id.*

Clark does not teach the use of criss-cross channels, nor any other eye fixation device beyond a "conventional" annular vacuum ring. Clark does not teach adjustment arms attached to an eye fixation portion. Clark does not teach the use of docking screws within an eye fixation device. Clark does not teach shutting off vacuum, recentering the eye fixation portion, and reapplying vacuum pressure. Clark does not teach a low-profile eye fixation portion which fits under the eye lid of a patient.

**Olson et al.** Olson teaches a device for transplanting a cornea. *Olson, Title & Abstract.* The device includes an eye fixation portion consisting of a conventional annular vacuum ring, or "suction ring", arrangement. *Olson, Fig. 1, #3, and col. 1, ll. 57-61.* Olson does teach the use of set screws to clamp surgical devices.

Olson does not teach the use of criss-cross channels, nor any other eye fixation device beyond a "conventional" annular vacuum ring. Olson does not teach X and Y translation guides or corresponding guide rods. Olson does not teach adjustment arms attached to an eye fixation portion. Olson does not teach discontinuing suction, repositioning the eye fixation apparatus, and re-applying suction.

**A. <u>The Section 103(a) Rejection of Claims 1 and 11 over L'Esperance or Hellenkamp</u>**

The Examiner rejected Claims 1 and 11 as unpatentable over L'Esperance or Hellenkamp. None of the references cited by the Examiner teach, suggest, or disclose in any way the use of criss-crossing channels for an eye-fixation apparatus. The Examiner has not even presented a *prima facie* case of obviousness. Nor has the Examiner cited any basis for the conclusion that a person of ordinary skill in the art would seek to modify the cited references to eliminate the vacuum annulus designs of the references, other than to argue that the prior art works just as well as Applicant's invention. This is in spite of the Affidavit of Dr. Will providing detailed recitations of the

problems caused by prior art devices such as those described by L'Esperance and Hellenkamp, as well as the numerous peer reviewed scientific papers demonstrating that prior art devices using annular vacuum rings cause complications due, at least in part to scleral displacement. The Examiner provides nothing to bridge the critical gap between the use of a hollow vacuum annulus and the use of criss-crossing vacuum channels other than simply disbelieving Dr. Will's extensive affidavit and other evidence addressing the differences between the claims and the cited references. The Examiner provides no evidentiary bases to refute the evidence submitted by Applicant.

Claims 1 and 11 include the express structural and functional limitation of criss-crossing vacuum channels. All the limitations of a claim must be considered when weighing the differences between the claimed invention and the prior art in determining the obviousness of a process or method claim. MPEP 2116.01; MPEP § 2143.03. Interpreting the claimed invention as a whole requires consideration of all claim limitations. MPEP 2116.01 To establish *prima facie* obviousness of a claimed invention, all the claim limitations as a whole must be obvious to a person of ordinary skill in the art. "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP 2143.03 (quoting In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)). Functional limitations must be given patentable weight, even if it is only these limitations which distinguish over prior art. DONNER at 479; In re Land, 368 F.2d 866, 151 USPQ 621 (C.C.P.A. 1966); In re Ludtke, 441 F.2d 660, 169 USPQ 563, 566 (C.C.P.A. 1971); In re Atwood, 354 F.2d 365, 148 USPQ 203, 210 (C.C.P.A. 1966).

The references L'Esperance and Hellenkamp do not disclose the combinations of elements recited in independent Claims 1, 11 and 12, nor has any reference been asserted teaching or suggesting such modification, and therefore the Examiner has not established a *prima facie* case of obviousness. None of the references discloses

apparatus or methods for an eye fixation apparatus utilizing *criss-crossing channels* on a convex bottom contact portion, without use of a vacuum annulus over the contact portion, nor do they disclose apparatus or methods capable of repositioning a vacuum-based eye fixation apparatus after vacuum has been applied initially. In fact, none of the references cited by the Examiner disclose use of criss-cross channels at all. The use of criss-cross channels distinguishes claims 1, 11, 22 and 12/11 over the Examiner's cited references.

The Examiner provides no basis for disputing Applicant's description of the cited references' weaknesses, other than to argue that the prior art patents are "presumed valid" so Applicant's invention cannot be an unobvious advance. Applicant has never argued that the Examiner's references are invalid, merely that they do not address or solve the problems solved by Applicant's inventions. Reference to Dr. Will's affidavits provides explanation of the unique features of the present invention, and the significant differences from the prior art cited by the Examiner. Nowhere does the Examiner cite any reference upon which to base his conclusory statements that Dr. Will is incorrect, or that prior art devices work so well that no subsequent improvements in the art are possible.

L'Esperance discloses a method and apparatus for modulating the flux distribution onto a surface to be profiled of an ablative radiation beam, including a fixation device which uses a porous membrane backed by a hollow vacuum chamber annulus. *See L'Esperance, Fig. 1 and col. 4, ll. 28-34* (describing "a hollow annulus.") L'Esperance does not focus on the fixation apparatus but rather on the laser ablation apparatus and methods, especially lensing methods. The description of the fixation means is simply a "hollow annulus, having a convergent axial end wall 11 of air-permeable material contoured to engage and retain an eye via a scleral-corneal region." *L'Esperance col. 4, ll. 25-35.*

L'Esperance does not disclose using criss-cross channels for distributing vacuum, nor any means for fixation not requiring "a hollow annulus." L'Esperance does not even address the problems of scleral damage caused by vacuum fixation devices. Therefore, L'Esperance does not render Applicant's solution obvious.

The Hellenkamp reference, cited by the Examiner, specifically discusses the problem of mucus accumulation which can occlude vacuum components, during procedures and after hardening, and which requires special cleaning procedures to remove. *First Will Aff. ¶ 5.h; Second Will Aff. ¶ 13.* The removable vacuum member in Hellenkamp is specifically intended as an attempt to address this problem, among others, but it is an incomplete solution at best. *See Hellenkamp, col. 5, ll. 43-5.* The Examiner states, "Applicant then states the 'criss-cross channels, providing alternating lands grooves, are fundamental to the present invention', however, there has been no showing of the criticality of this particular arrangement of voids and barriers." *OA 04112007 at p.10.* Applicant submits that this is the focus of much of the application itself – it is one of the stated advantages over existing devices. Moreover, Dr. Will's affidavits discuss the differences, and resulting advantages, of his criss-cross channels over existing devices such as L'Esperance and Hellenkamp in detail. The language the Examiner cites states merely that the particular orientation of the criss-cross channel intersections is not limited to the preferred embodiment.

The Examiner's definition of a porous membrane as simply comprising alternating lands and grooves is unsupportable. *OA 04112007 p. 10-11.* A porous membrane requires flow paths from the contact surface through the membrane and open to the back-side surface. It *requires* a *permeable* membrane. A permeable membrane is not in any manner the same as alternating lands and grooves created by a criss-cross vacuum channel. The Examiner needs to cite some objective source for this claimed equivalence and cannot simply declare it so.

The Examiner referenced an article by Benitez-del-Castillo et al, *Decrease in Tear Secretion and Corneal Sensitivity After Laser In Situ Keratomieusis*, CORNEA, vol. 20(1), January 2001 at pp. 30-32 (*OA 06142007 at pp. 7-8*). The reference, a copy of which was provided by the Examiner, does not profess to answer the causes of dry eye complications after LASIK, it merely confirms that such complications do indeed occur. Applicant's invention, as explained in the Specification, seeks to address some of the causes of complications and less than optimal outcomes. The Examiner's article reference does not obviate the different approach that Applicant has taken to solve these problems.

Hellenkamp discloses an eye fixation apparatus utilizing an annular hollow vacuum ring with a vacuum ring insert to prevent complete occlusion of vacuum caused by chemosis or buildup of mucous in the vacuum ring. The vacuum ring insert simply is intended to prevent complete occlusion, not prevent damage such as chemosis. *Hellenkamp col. 5 ll. 25-30* ("to maintain the suction channel evacuated even in the presence of chemosis"). Thus Hellenkamp does not solve the problem of chemosis and damage, it merely attempts to deal with the problem as it relates to loss of vacuum. Hellenkamp, however, acknowledges that damage does occur from the operation of annular vacuum rings.

The Examiner states, "Both L'Esperance (EP '127) and Hellenkamp teach a device and method as claimed except for the criss-cross passages." *OA 06142006 p.5.* The criss-cross channels, providing alternating lands and grooves, are fundamental to the present invention, and are not disclosed by the cited references. L'Esperance and Hellenkamp do not disclose means for fixing an eye for surgery other than a hollow annulus. A hollow annulus has specific disadvantages not appreciated by either L'Esperance nor Hellenkamp which are addressed by the present invention, as pointed out by the accompanying Affidavit of Dr. Will. Several journal articles discussing

complications caused by use of vacuum rings such as taught in Hellenkamp, Curtin and Clark, are addressed in the *Second Aff. Will, ¶¶ 6-11 and Exh. 1-6.* The articles were provided to the Examiner to address the Examiner's skepticism that prior art devices caused complications in surgery. The articles demonstrate that the problems which Applicant seeks to address are real world problems, and not mere "speculation" as asserted by the Examiner (without basis). *OA 04112007 p. 8.*

The Examiner's rejections appear to be based on a view that the Applicant is required to prove that the references cited by the Examiner are non-functioning, or that such references must be presumed full proof and without significant drawbacks, in order to claim an invention with improved results over the existing art. The burden lies with the Examiner to demonstrate that Applicant's invention is obvious through citation to record evidence rather than simply relying on conclusory statements that he is "unconvinced." The Examiner states that because L'Esperance and other references are patents they are "presumed valid" and therefore L'Esperance's porous membrane does not clog. *OA 06142007 at p.8.* Applicant submits that the Examiner misapprehends the difference between patent validity and perfection. The mere fact that a patent is presumed valid does not imply that such a patent solves, perfectly and forever more, all problems associated with the field of art such that no new patentable device may ever issue in the future.

Needless to say, there is likely more than one cause of "dry eye" after LASIK, and Dr. Will is not required to disprove the Examiner's thesis in order to establish that his invention reduces potential for this complication, and that a potential source of the complication is damaged sclera caused by conventional vacuum rings. A copy of the Albietz reference cited in the *First Will Aff., ¶ 8, and Second Will Aff. ¶ 10 and Exhibit 5.* The purpose of the reference is to demonstrate that problems do exist with existing annular vacuum ring designs such as Hellenkamp.

The difficulty in cleaning is discussed as a general hindrance which can reduce the patient turnover rate. *See Hellenkamp, col. 3, l. 45 – col. 4, l. 12.* The same difficulties with clogging and effective cleaning described in Hellenkamp are magnified in a porous membrane as taught by L'Esperance. Additional drawbacks include higher risk of patient cross-contamination with viral, bacterial and prion material. *First Will Aff. ¶ 5.h.* The present invention provides a relatively smooth and impermeable surface with shallow cross-connected channels which are easily cleaned using conventional methods, thereby extending the life of the apparatus. The cross-connection prevents loss of vacuum from occlusion of any single channel due to buildup.

Additionally, the hollow annulus designs inherent to L'Esperance and Hellenkamp require the use of a lid speculum on patients with narrow ocular orbits. *First Will Aff. ¶¶ 7-8; Second Will Aff. ¶¶ 15-17* . The use of lid specula causes undesired negative side effects which have been documented, and are an ever increasing problem as procedures such as LASIK become more widespread. Dr. Will's Affidavit specifically addresses the complications caused by conventional hollow annulus apparatus. The use of criss-cross channels with alternating lands and grooves in the present invention avoids the need for lid speculum even in patients with narrow orbits because it allows a lower profile device. Examiner failed to point to any reference which teaches criss-cross vacuum channels, creating a low profile apparatus which can fit underneath the eyelids, obviating the need for a lid speculum during surgery. All of the art cited by the Examiner relies upon an annular design necessitating a vault, with the exception of Ruiz, which does not teach the use of a vacuum fixation apparatus at all and so does not support a rejection.

The use of criss-cross channels minimizes distortion of the eye lens which causes less than optimal correction to patients' vision. The criss-cross channels prevent or minimize damage to the cornea, sclera and conjunctiva which has been a

documented problem in LASIK and other keratome procedures using apparatus such as relied upon by the Examiner. The criss-cross channels permit a low-profile device which can fit under patients' eye lids, obviating the need for a lid speculum, thereby reducing complications in patient recovery and reducing obstructions during surgery. These complications are especially relevant for patients with narrow ocular orbits. Dr. Will's Affidavit also provides citation to references which provide objective evidence to back up his explanations of the differences and advantages of his invention over the prior art demonstrating the nonobviousness of the claims. *First Will Aff. ¶¶ 7-8.*

The Examiner incorrectly states that there is no disclosure in the Application relating to holding the corneal surface flat, without displacement into the criss-cross vacuum channels. *OA 07142006 at p. 3.* The original specification at page 6, lines 12-20, states:

> "When placed on the eye, with the contact portion **14** contacting directly upon the eye and encircling the cornea, the criss-crossing channels **16** are upon the eye globe conjunctiva. Vacuum port **18** communicates with channels **16** such that vacuum pressure exerted at the vacuum port **18** creates vacuum pressure in the criss-crossing channels **16**, *sucking the eye globe conjunctiva attached to the sclera flush against the contact portion **14**.* This fixates the eye. The criss-crossing channels **16** work to oppose the suction created by each other, such that *the eye glove conjunctiva attached to the sclera, is spread taut between the channels **16**, instead of being sucked upon into a particular channel*."

*Specification, page 6, lines 12-20 (emphasis added).* Further, the Specification's "Summary of the Invention", at page 4, lines 11-21, recites decreased trauma to the ocular surface and the ability to more easily reposition the fixation device after vacuum has once been applied as specific advantages of the present invention. Further, Dr. Will's accompanying Affidavit provides further evidence in this regard. In contrast, the Hellenkamp reference relied on by the Examiner specifically acknowledges that the cornea is displaced into the hollow vacuum ring to contact the surface of the vacuum enhancer. *Hellenkamp at col.9, ll. 23-43.* Conversely, the Examiner provided no record

evidence to support his incorrect factual assertion that the present invention does not draw the cornea surface to contact against the flat land between the criss-cross channels, rather than into the channels themselves, as claimed and described.

Additionally, the use of criss-cross channels (a recited element of each claim) avoids the problem of clogging which porous surfaces (such as taught in L'Esperance) are subject to. The use of channels also permits a lower profile than devices using a porous surface can achieve because there is no need for the vacuum annulus above the porous surface (as taught in L'Esperance). Thus, the present invention provides unobvious solutions to the problems inherent in existing apparatus and methods.

Although specific vacuum pressures are not claimed, the ability to use lower vacuum pressure for eye fixation is an advantage of the criss-cross vacuum channel design over prior art structures which is evidence supporting the non-obvious differences over the structures disclosed in the cited references.

The Affidavit of Dr. Will directly addresses the inherent problems with existing devices and methods and the specific structures and methods which solve these problems. *First Will Aff. ¶¶ 5-9; Second Will Aff. ¶¶ 6-15.* The references submitted with the Second Will Aff. discuss complications from current LASIK and other ophthalmological surgical procedures, and indicate that the use of vacuum rings may be a significant, though certainly not the only, cause. *Second Will Aff. ¶¶ 6-15, Exhibits 1-6.* Applicant has made clear that a significant disadvantage of existing designs such as Hellenkamp, Curtin, and others is that they rely on a hollow annular ring to apply vacuum, which causes the cornea surface to displace into the vault of the ring. The vacuum enhancer taught by Hellenkamp reduces this problem in certain respects, but does not eliminate it. Applicant has also explained that the vault – inherent in the design of existing hollow annular rings, including Hellenkamp, Curtin and L'Esperance – creates the need for a lid speculum during procedures, which is generally eliminated by the low

profile of the criss-cross channel design which is recited in all claims of the present invention. Applicant, by pointing out these specific drawbacks of existing apparatus and methods, does not argue that these references are inoperative or invalid, but merely that they are not perfect solutions. The present invention represents a significant improvement over existing apparatus and methods in many respects, discussed in detail in Dr. Will's Affidavit. The Examiner incorrectly implies that by claiming improvement over the existing art Applicant must prove the existing art lacks utility.

Pores are not lands and grooves.

The Examiner describes the pores of L'Esperance as lands and grooves but cites no support for this. *OA 06142007 at pp. 10-11.* A porous surface would necessarily be considered smooth, lacking lands and grooves. Referring to L'Esperance's porous surface as lands and grooves extrapolates the minimal teachings of L'Esperance much too far. L'Esperance teaches a porous, air-permeable membrane. This is not equivalent to criss-crossing channels creating lands and grooves. L'Esperance applies suction through a porous membrane via an annular chamber above the porous membrane. *See L'Esperance '127 at col.4, ll.26-34.* This is the only method taught by L'Esperance '127 and its related applications.

The Examiner correctly notes that the porous surface of L'Esperance distributes vacuum over its surface to improve stability. However, such porous surfaces are subject to clogging. All porous materials are subject to clogging if mucous is sucked through them, a simple fact of nature. Examiner cited nothing in L'Esperance or any other reference suggesting special properties which render L'Esperance's porous membrane not subject to clogging. Rather than placing the burden on Applicant to find a reference describing L'Esperance's shortcomings, the burden rests with the Examiner to cite a reference explaining how Dr. Will's description of L'Esperance's tendency to clog is not correct. The fact that L'Esperance does not address this problem does not render it

inapplicable – L'Esperance was primarily focused on issues unrelated to the eye fixation methods. Hellenkamp addresses significant problems with buildup of mucous and other debris within vacuum channels leading to occlusion. The Examiner fails to explain how the pores of L'Esperance are free of clogging issues whereas the full bore annular vacuum rings of Hellenkamp are subject to occlusion. Dr. Will stated in his affidavit that based on his experience conducting surgeries that the porous membrane of L'Esperance would be subject to clogging. *First Will Aff. ¶ 9*.

The Examiner states, "It is not clear to the examiner why" a low profile device obviates the need for a lid speculum. *OA 06142007 at p. 6.* Applicant addressed this question in the *Second Will Aff. ¶ 14-16* . Devices relying on a vaulted vacuum annulus, such as L'Esperance and Hellenkamp, require use of a lid speculum. *Id.* Dr. Will has performed thousands of eye surgeries. Respectfully, Applicant submits that if the Examiner disputes facts in Dr. Will's affidavit then the burden rests on the Examiner to prove his contentions based on references which can be made part of the record, so that Applicant may respond and reviewing bodies can review the evidence. Moreover, Dr. Will stated that based on his direct experience, that of his staff, and his research, existing devices operating similar to L'Esperance and Hellenkamp face limitations which the present invention addresses. *Second Will Aff.* ¶¶ 2-4. Applicant submits that the Examiner failed to cite reliable references in the record.

The Examiner states that L'Esperance's membrane forms only "a portion" of the device but extends beyond the annular chamber and so would fit under the eye lid. *OA 06142007 at p. 7.* Applicant points out that this extending lip does not convey vacuum as there is no vacuum source above it. A membrane would conduct vacuum only through its plane, not laterally. Thus the annular chamber necessarily is concurrent in area with the vacuum-affected surface of the membrane. The annular access provided for surgical access is inside the inner diameter of the vacuum annulus. By contrast, as

pointed out in Dr. Will's affidavits and the Specification and Drawings, the criss-crossing channels extend from the annulus provided for surgical access outward, with no vacuum annulus above them. The criss-cross channels therefore provide an inherently lower profile. Again, neither L'Esperance nor Applicant's figures are drawn to scale so the Examiner's attempts to measure proportions is inappropriate. One can observe the structures and note that there is indeed, necessarily, a vacuum annulus extending vertically above the membrane of L'Esperance (*see Fig. 1, #10, 11, 12 & col. col. 4 ll. 28-35*), while the vacuum channels of claims 1, 11 and 22 extend laterally with no vertical vacuum annulus rising above, allowing a narrow profile for an eyelid to fit over (see Fig. 4).

The Examiner equates the vacuum distributor inside the suction ring of Hellenkamp equates to the distributed lands and grooves created by the criss-crossing channels of claims 1, 11 and 22. *OA 06142007 at p. 5.* The problem with the Examiner's evaluation is that in Hellenkamp the sclera does not contact the surface of the insert *until it has been sucked into the annulus of the vacuum ring* – thus substantially all of the damage has already been done. Nowhere does Hellenkamp teach, nor do the drawings of Hellenkamp illustrate, a flush-mounted land and groove contact surface. Hellenkamp never contemplated a solution involving anything other than a vacuum ring. Moreover, Hellenkamp merely attempts to distribute vacuum more evenly – but this is only a partial solution. The real damage is caused by displacement into the vacuum ring itself, which Hellenkamp does not prevent. L'Esperance, while able to prevent displacement has the potential of causing the opposite problem. If the pores of L'Esperance clog then either of two outcomes is likely. Either vacuum hold will be lost, allowing the fixation apparatus to move or separate completely from the cornea, or, the clogged pores will lock the vacuum between the membrane surface and the conjunctiva with no way to break the vacuum. The result is that the apparatus must be

separated under vacuum potentially tearing the sclera. Either outcome is undesirable. The criss-cross channels of Applicant's invention prevent displacement into a annular vacuum ring without the danger of clogging created by L'Esperance's membrane.

The lands of the criss-crossing channels provide the contact surface without being drawn into an annular ring. The vacuum channels are on opposing sides of any given land such that they act against one another to pull the sclera against the lands between rather than displacing into the channels themselves.

The prior art teaches away from non-use of lid specula and lowering IOP.

Both Hellenkamp and L'Esperance teach vacuum rings with annular vaults requiring the use of lid specula causing greater discomfort for patients. *See First Will Aff. at ¶ 8.* L'Esperance '172 (cited by the Examiner), which is a continuation-in-part of Application 891,285 issued as L'Esperance '148 (also cited by the Examiner), specifically teaches the requirement of using a lid speculum and can therefore be viewed as teaching away from apparatus and methods which do not require such. *See L'Esperance '172, col.3, ll.50-59.* "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 45 USPQ2d 1977 (Fed. Cir. 1998). *See also* The Dow Chemical Co. v. U.S.,18 USPQ2d 1657 (Ct. Cl. 1990). The use of criss-crossed channels with alternating lands and grooves, a recited element in all claims of the present invention, eliminates the need for annular vaults thereby creating a lower profile device. This lower profile eliminates the need for a lid speculum in most cases, and is more comfortable for patients, especially those with narrow or tight lid openings. This fundamentally distinguishes the present claims from L'Esperance.

The use of the criss-cross channel design also reduces deformation with the goal

of fixating the eye while minimizing raising IOP. This is in direct contrast to the teachings of the prior art which teach increased IOP as desirable. *Hellenkamp col. 8, ll. 54-64; Second Will Aff. ¶ 18 and Exh. 1-6.*

The Examiner must provide an affidavit to rely upon personal knowledge.

Applicant does not argue that the prior art cited lacks utility or is non-functional, but the present invention provides unobvious improvements over the cited references which achieve greater accuracy and less discomfort from patients, while making laser keratome procedures more economical for practitioners.

Further, if the Examiner relies on personal knowledge to assert that:

(1) L'Esperance and Hellenkamp are not subject to clogging or occlusion;

(2) neither L'Esperance nor Hellenkamp cause damage to the cornea/conjunctiva surface when vacuum is applied and removed; and,

(3) that use of high profile hollow annular rings as taught by the Examiner's cited references does not cause complications and discomfort to patients;

then the Examiner is required to provide an affidavit explaining the basis of such knowledge. *See* MPEP 2144.03(A) [R-1] ("It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based.: (omitting citations)). Further, "While 'official notice' may be relied on, these circumstances should be rare when an application is under final rejection..." MPEP 2144.03(A) [R-1].

> "It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at

> 420-21. See also *In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979)"

MPEP 2144.03(A) (emphasis original). "If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. *See* 37 C.F.R. 1.104(d)(2)." MPEP 2144.03(C) [R-1] (emphasis added). Furthermore, Section 103 requires analysis of a claimed invention as a whole:

> "Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness."

Gillette Co. v. S.C. Johnson & Son Inc., 16 USPQ2d 1923 (Fed. Cir. 1990).

**B. The Rejection of Claim 12 over L'Esperance or Hellenkamp**

Applicant reiterates the arguments in Section A, above.

The Examiner also asserts that "to discontinue vacuum and reposition the apparatus if it is not centered on the cornea [is obvious], since proper positioning of the corneal flap is critical..." *OA July 14, 2006, at p. 5.* This simply misses the point. The apparatus and methods of the references cited by the Examiner actually *prevent* discontinuation of vacuum and repositioning of the apparatus due to the negative effects of using a hollow annulus to apply vacuum, as explained by the First and Second Will Affidavits. All of the discussion relating to the damage created by vacuum rings caused by scleral displacement into the vacuum ring chamber have been addressed above. The damage caused by vacuum rings prevents repositioning after application of vacuum. *First Will Aff.* ¶ *5.*. L'Esperance is subject to clogging which can cause the apparatus to adhere to the sclera even after vacuum pressure is removed. *First Will Aff.* ¶ *9.a.* These dangers are alleviated by the method recited in claim 12/11 - the use of criss-cross channels avoids the "hickey" effect and prevents post-vacuum adherence. Thus, the Examiner's arguments regarding obviousness actually demonstrate the nonobviousness

of using a system of criss-cross channels providing alternating lands and grooves. In addition, L'Esperance and Hellenkamp retain the significant disadvantage that they require lid speculum during most procedures (due to the inherently high profile of the hollow annulus), especially for patients with narrow ocular orbits, and they contain no teachings to indicate a solution. Other disadvantages of the L'Esperance and Hellenkamp references, which are addressed by the present invention, are made apparent by the accompanying Affidavit of Dr. Will.

The Examiner states that both L'Esperance and Hellenkamp teach the device as claimed "except for the criss-cross passages" and use of such channels is obvious because "this is another configuration that would serve to distribute vacuum and thus provides no unexpected results." *OA 07112008 p. 9.* The Examiner went on to say that to "discontinue the vacuum and reposition the apparatus" is also obvious. This is clear hindsight analysis, and requires the Examiner to completely disregard the Applicant's affidavits, as well as the entire Specification and Claims. Applicant explained, in detail, based upon years of experience and thousands of procedures, and a thorough knowledge of prior art devices, that apparatus using the annular vacuum rings of Hellenkamp or the annular chamber and porous membrane of L'Esperance, prevent the discontinuance of vacuum and repositioning of the fixation apparatus. The references cited therefore do not render such a method obvious, as they preclude such a method. The Examiner simply discounts the Applicants submission without citation to any reference nor any affidavit by the Examiner. The Examiner must produce evidence of record.

**C. The Rejection of Claims 2 and 13 over L'Esperance or Hellenkamp in combination with Curtin.**

Applicant reiterates the arguments in Sections A & B, above.

Dependent Claims 2 and 13 were rejected under § 103(a) as unpatentable over

L'Esperance or Hellenkamp in combination with Curtin. Traversal with respect to L'Esperance or Hellenkamp is reasserted regarding independent claims 1, 11 and 12 and further with regard to their combination with Curtin, which teaches a conventional hollow annular ring. *Curtin, col.5, ll. 46-51.*

The Examiner asserts that "Curtin teaches the use of adjustment arms on eye fixation devices." *OA 07112008 at p.10.* Applicant respectfully disagrees. Curtin specifically teaches that the rigid vacuum tube 128 holds annular ring 124 stationary over an eyeball, at which point the patient is provided a target to focus on which aligns the eye to the apparatus. Vacuum is applied to annular ring 124 which then "locks the ring arrangement 122 on the patient's eye when the patient's visual axis is aligned with the target." *Curtin, col.6, ll. 1-8; col. 7, ll. 29-39 & 63-68.* Curtin does not, alone nor in combination with other references cited, teach or suggest the use of adjustment arms connected to an eye fixation apparatus which permit adjustment of the apparatus to the eyeball prior to fixation, rather than having the eyeball align itself to a vacuum ring. Thus Curtin teaches exactly the opposite methodology of the current invention recited in claims 2, 13 and 22, which renders it less optimal than the current invention.

Dr. Will, in his affidavit, notes several advantages from the use of adjustment arms. *See First Will Aff. ¶ 10.c.* Maneuvering the device is easier, and there is less chance that inadvertent contact will scratch the conjunctival surface or cause contamination. While the single adjustment arm of Curtin may have 3-D adjustment capability as argued by the Examiner, such capability does not equate to the ease of use provided by the arms of the present invention which would allow a surgeon to grip the arms with each hand while sighting through the annular access hole with a sighting device, rather than the cumbersome apparatus described in Curtin. A person of skill in the art would not see the combination of Curtin with L'Esperance and/or Hellenkamp as teaching the combination of elements of claims 2 and 13.

**D. The Rejection of Claims 3, 4, 7, 8, 14, 15, 18 and 19 over L'Esperance or Hellenkamp in combination with Curtin and Clark.**

Applicant reiterates the arguments in Sections A through C, above.

Dependent Claims 3, 4, 7, 8, 14, 15, 18 and 19 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin and/or Clark et al.

The Examiner incorrectly states that "Clark et al teach employing X- and Y- axis adjustment mechanisms on eye fixation devices." *OA 07142007 at p.15.* Applicant respectfully disagrees. Applicant has not claimed the concept of X-Y adjustment, but a particular apparatus and method of lateral and cross-lateral position adjustment integrated into an eye fixation portion for use during surgical procedures.

As makes clear in the *First Will Aff.*, the ability to adjust the fixation apparatus to the eyeball, rather than vice versa, provides for better adjustment and concentration properties during laser procedures. This adjustment capability is enhanced by the addition of lateral translation members directly to the eye fixation apparatus. Translation guide rods with knob adjusters allow precise adjustments while requiring less manual dexterity than current apparatus and methods. The translation guide rods also prevent further distortion of the eyeball caused by forcing the eyeball into alignment with the surgical apparatus.

1. Claims 3 and 14 over L'Esperance or Hellenkamp, Curtin and Clark.

The Examiner argues that "Curtin teaches the use of translation rods and adjustment knobs to allow the adjustment in 3 dimensions of an ophthalmic surgical instrument." *OA 07112008 at p.10.* However, the mere ability to move through space does not render obvious a structure including translation guide members connected to an eye fixation apparatus and their methods for use.

Applicant's claims are drawn to *annular* X and Y translation members (Fig. 5, #40, #60) connected to the eye fixation portion (Fig. 5, #12) of an eye fixation apparatus, and methods to use these translation guide members. Curtin teaches an apparatus for moving surgical instruments separate from the fixating vacuum ring rather than connected to it, an apparatus which is not annular in any way. *Curtin Fig. 1, #16, #32.* Nothing in Curtin teaches annular X or Y translation guide members adjustably connected to an eye fixation portion as recited in claims 3, 7, 14 and 18. The "eye fixation portion" (#12) as recited in the claims refers to the lower part of the eye fixation apparatus, the part which actually contacts the patient's eyeball.

Clark discloses a microscope apparatus for bench aligning a microkeratome blade. Clark The microscope target table includes the ability to move in an X-Y orientation, but the structures do not disclose and do not equate to annular translation guide members connected to an eye fixation device - i.e. on a patient's eye - for surgery. Clark, Fig. 23, discloses a keratome blade device moving across a surface in a single direction, but the keratome device is not an *annular* translation guide member, and is adjustable only in the vertical direction. The blade of Clark does not disclose the same structure, nor the same function or effect, as the annular translation guide member recited in claims 3 and 14.

2. Claims 7 and 18 over L'Esperance or Hellenkamp, Curtin and Clark.

Applicant reiterates the arguments in Section D.1, above.

Applicant reiterates the arguments above. Curtin does not teach a translation guide member connected to an eye fixation portion. Even if one were to interpret Clark as teaching a translation guide member connected to an eye fixation portion, Clark is silent regarding any additional utility of a second translation guide member.

3. Claims 4, 8, 15 and 19 over L'Esperance or Hellenkamp, Curtin and Clark.

Applicant reiterates the arguments in Sections D.1 through D.2, above.

Additionally, neither Curtin nor Clark teach the use of translation guide rods and adjustment knobs to adjust one or more translation guide members connected to an eye fixation portion as recited in claims 4, 8, 15 and 19.

Applicant acknowledges the Examiner's explanation of how adjustment screws operate, but this does not render the claims obvious. *OA 04112007 at pp. 9-10.* The statement that the Examiner refers to is at *First Will Aff. ¶ 11*, where he refers to the fact that seemingly minor changes in apparatus and methods can actually achieve significant results in surgical procedures where "adjustments in the sub-micron range" can alter outcomes. The reference was to all of the differences over the prior art in the previous ten paragraphs. Thus, the reductions in eye deformity, intraocular pressure variations, reductions in hydration variation of the cornea, improved positioning capabilities, improved re-positioning capabilities, improved adjustment capabilities, and lessened complications achieved by the apparatus and methods claimed, all lead to significantly improved outcomes individually and cumulatively. The point was that improvements over prior art devices in positioning or focusing LASIK apparatus may, in some cases, only be in the sub-micron range, but even such small *improvements* can be significant.

In addition, Dr. Will's affidavit makes clear the differences between the present invention and the asserted references. X-Y adjustment ability for adjusting surgical apparatus prevents further distortion of the eyeball caused by forcing the eyeball to alignment with the apparatus, rather than vice versa. It also eliminates the need for expensive and complicated software to adjust for laser offset.

4. Claim 16 over L'Esperance or Hellenkamp, Curtin and Clark.

Applicant reiterates the arguments in Sections D.1 through D.3, above.

Additionally, neither Curtin nor Clark disclose a method of using docking screws for tightening against objects within an annular translation guide member. The vacuum

ring of Curtin has no means of connecting an annular translation guide member, nor of tightening a docking screw against objects inserted into the vacuum ring. *Curtin, Fig. 1, #124.* Nor does Clark disclose any set screw for tightening against and object within an annular translation guide member. *Clark, Fig. 23, #37, #39.* Therefore, the Examiner has not established a *prima facie* case of obviousness.

5. The Rejection of Claims 5, 6, 9, 10, 17 and 20-22 over L'Esperance or Hellenkamp and Curtin and Clark, and in addition Olson.

Applicant reiterates the arguments in Sections D.1 through D.4, above.

Dependent Claims 5, 6, 9, 10, 16, 17, 18 and 19 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp and Curtin in combination with Clark et al, and further in regard to U.S. 6,613,061 Olson. Applicant acknowledges that Olson teaches the use of docking screws. Applicant does not claim to have invented docking screws, but the claims as a whole incorporating docking screws are novel and unobvious in combination with annular translation guide members adjustably connected to an eye fixation portion.

None of the cited references, even in combination, teach all the elements of the rejected claims. Applicant reiterates the discussion above, relating to the lack of teaching of first and second annular translation guide members in the cited references. Olson does not teach the use of docking screws to tighten against objects inserted into the cylindrical space formed by the first (or second) annular translation guide members.

The Examiner's additional reliance on Ruiz does not disclose the elements of the claim either. Ruiz teaches a geared cutting blade on a base which lacks the ability to fix the eye in space, and so still fails to disclose, even in combination, all of the elements of the rejected claims. Ruiz does not disclose use of docking screws to tighten against objects in the annulus, especially considering Ruiz teaches a movable cutting blade. Nor does Ruiz teach the use of a second translation guide member non-parallel to a first

translation guide member to permit X-Y adjustments with a docking screw.

Notably, Olson teaches the use of a conventional vacuum ring for eye fixation. *Olson Fig. 1 #4 & 5; col. 1, ll. 55-60.* This is yet another reference teaching the use of vacuum rings, in contrast to the criss-cross channel design of Applicant. The Examiner failed to establish a *prima facie* case of obviousness under Section 103(a).

In addition, Dr. Will's affidavit makes clear the differences between the present invention and the asserted references. X-Y adjustment ability and the use of docking screws for setting and adjusting surgical apparatus prevents further distortion of the eyeball caused by forcing the eyeball to alignment with the apparatus, rather than vice versa. It also eliminates the need for expensive and complicated software to adjust for laser offset. The claims are unobvious.

**E. <u>The Rejection of Claim 22 over L'Esperance or Hellenkamp and Curtin and Clark, and in addition Olson.</u>**

Applicant reiterates the arguments in Sections A through D, above.

Independent Claim 22 stands on its own. The Examiner rejected claim 22 under § 103(a) based on a combination of L'Esperance or Hellenkamp in combination with Curtin and Clark et al, and further in combination with Olson. Claim 22 includes all of the structural elements of claims 1-10 but explicitly recites the limitation "wherein the eye fixation portion has a low profile convex bottom contact portion..." and "...is substantially narrow so as to fit under the eye lid of a patient without the use of a lid speculum." Support for claim 22 is found in the Specification at page 4, ll. 11-14 and Fig. 4. The Specification, at page 4, lines 11-14, describes a feature of the invention that "(1) functions without the need for a lid speculum; (a) low profile fits comfortably under the lids; (b) can more easily be used on patients with "tight lids" which are common to some races..."

Applicant reasserts each of the arguments regarding rejections of claims 1-21,

above, in regard to Claim 22. None of the cited references, even in combination, discloses all of the elements of claim 22 much less discloses the combination of the elements. Specifically, the references do not disclose a low profile fixation portion with criss-cross channels, first and second translation guide members with adjustment rods and knobs, docking screws in the first and second translation guide members, wherein the profile of the fixation portion – i.e. the structure containing the vacuum channels – is low enough to fit under the eye lid of a patient to obviate the need for a lid speculum.

**F. Method Claims 11-21.**

Applicant asserts that method claims 11-21 stand on their own. The Examiner cited no reference or combination of references which recite the steps of method claims 11-21, but has merely cited references which include some, but not all, structural elements of apparatus claims 1-10. Applicant here reasserts all of the arguments relating to apparatus claims 1-10 relating to structural limitations inherent in claims 11-21, and additionally argues that the method steps are not disclosed by any combination of references, nor are they disclosed by any obvious modification of such references. Therefore, even if apparatus claims 1-10 and 22 are held obvious, Applicant submits method claims 11-21 are not thereby rendered obvious and stand on their own.

**SUMMARY**

For the foregoing reasons, Appellant requests withdrawal of Examiner's rejections of Claims 1-22 and allowance.

Respectfully submitted,

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